

CLAIMS

What is claimed is:

1. A transdermal formulation comprising a drug reservoir and an effective amount of lasofoxifene and pharmaceutically acceptable salts thereof.
- 5 2. The transdermal formulation of claim 1, further comprising an effective amount of a drug permeation enhancer.
3. A transdermal formulation comprising an adhesive drug matrix reservoir and an effective amount of lasofoxifene and pharmaceutically acceptable salts thereof.
4. The transdermal formulation of claim 3, wherein the adhesive matrix is a solvent
10 based pressure sensitive adhesive matrix.
5. The transdermal formulation of claim 3, wherein the adhesive matrix is a water based pressure sensitive adhesive matrix.
6. A transdermal formulation comprising a liquid reservoir drug reservoir and an effective amount of lasofoxifene and pharmaceutically acceptable salts thereof.
- 15 7. A transdermal formulation comprising a free form hydroalcoholic gel and an effective amount of lasofoxifene and pharmaceutically acceptable salts thereof.
8. The transdermal formulation of any of claims 3 to 7, further comprising an effective amount of a drug permeation enhancer.
9. The transdermal formulation of claim 8, wherein the drug permeation enhancer
20 is an effective amount of cell-envelope disordering compound.
10. The transdermal formulation of claim 9, wherein the cell-envelope disordering compound comprises an effective amount of a lower alkanol.
11. The transdermal formulation of claim 8, wherein the drug permeation enhancer comprises an effective amount of a lower alkanol and an effective amount of
25 glycerol monooleate.
12. The transdermal formulation of claim 11, wherein the effective amount of glycerol monooleate is about greater than or equal to 0.01 % w/w.
13. A transdermal device comprising a means for adhering the drug reservoir to the application situs and the pharmaceutical formulation of any of claims 3 to 7.

14. A device for administering an active agent to the skin or mucosa of an individual comprising a laminated composite of:
- a. a backing layer defining an upper portion of a reservoir and extending to the periphery of a peel seal disk;
 - 5 b. an active agent-permeable membrane extending to the periphery of the peel seal disk and the backing layer, and underlying the backing layer, the backing layer and membrane defining;
 - c. the reservoir therebetween that contains the formulation of claim 1;
 - 10 d. the peel seal disc underlying an active agent-permeable membrane;
 - e. a heat seal about the periphery of the peel seal disc, the active agent-permeable membrane and the backing layer;
 - f. an adhesive overlay having a central portion overlying the
15 backing layer and a peripheral portion that extends beyond the periphery of the peel seal disc; and
 - g. a removable release liner underlying the peripheral portion of the adhesive overlay and the peel seal disc.
15. A method for treating or preventing a disorder associated with estrogen
20 deficiency or dysregulation in a subject comprising contacting an application situs of the subject with an effective pharmaceutical formulation of claim 1.
16. A method for treating or preventing a disorder associated with estrogen deficiency or dysregulation in a subject comprising contacting an application situs of the subject with an effective pharmaceutical formulation of claim 2.
- 25 17. A method for treating or preventing a disorder associated with estrogen deficiency or dysregulation in a subject comprising contacting an application situs of the subject with an effective pharmaceutical formulation of any of claims 3 to 7.

18. A method for treating or preventing a disorder associated with estrogen deficiency or dysregulation in a subject comprising contacting an application situs of the subject with the device of claim 14.
19. A method for treating or preventing a disorder associated with estrogen deficiency in a subject comprising contacting a dermal situs of the subject with the device of claim 14.
- 5

11/11/2019 10:11:11 AM